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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,561	04/18/2001	Bradley Michael John Stringer	2240-1-001DIV1 CON	1047

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EXAMINER

KETTER, JAMES S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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8

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Commissioner of Patents and Trademarks

--See attached--

Office Action Summary

Applicant(s)

09/837,561

Applicant(s)

STRINGER, BRADLEY MICHAEL
JOHN

Examiner

James S. Ketter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☒ Claim(s) 6-10, 13-22 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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In view of the confusion expressed by Applicant over the restriction requirement set forth in the previous Office Action, paper No. 4, mailed 25 September 2002, all inventions in all claims are hereby rejoined. Thus, no restriction requirement is extant.

Claim 26 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 26 merely recites a limitation of the cells or cell-lines to human. However, claim 22 is already clearly thus limited. Claims 23-25, being omnibus type claims (see rejection under 35 USC§ 112, second paragraph, below, are of unclear scope, and thus may or may not have been intended to be limited to human cells or cell-lines.

Claims 6-10, 13-22 and 26 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). The claims have been further treated on the merits in the interest of compact prosecution. However, to be fully responsive to this Office Action, Applicant must make the appropriate correction to the instant claims.

Claim 17 is objected to because of the following informalities: the comma at line 1 is inappropriate. Appropriate correction is required.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that they fail to point out what is included or excluded by the claim language. These claims are omnibus type claims.

Claim 27 provides for the use of the recited cells, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 27 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 13-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-19 of U.S. Patent No. 6,340,592, as follows: instant claims 1, 2, 6 and 27 over patented claim 1; instant claims 3 and 4 over patented claim 2; instant claim 5 over patented claim 3; instant claims 7-10 over patented claims 5-8, respectively; instant claims 13 and 17 over patented claim 9; instant claims 14-16 over patented claims 10-12, respectively; instant claims 18-23 over patented claims 13-18, respectively; and instant claims 24-26 over patented claim 19. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the patented claims.

Claims 1-10 and 13-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-19 of U.S. Patent No. 6,197,585, as follows: instant claims 1, 2 and 27 over patented claim 1; instant claims 3 and 4 over patented claim 2; instant claims 5-10 over patented claims 3-8, respectively; instant claims 13-17 over patented claims 9-13, respectively; instant claims 18-23 over patented claims 15-20, respectively; and instant claims 24-26 over patented claim 21. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the patented claims.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10, 13, 14, 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Harris et al. (A, newly cited).

Claims 1-10, 13, 14, 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Harris et al. (A, newly cited).

Harris et al. teaches, e.g., at column 10, last paragraph, the transfection of hFOB (human fetal osteoblasts) with a construct expressing a temperature-sensitive allele of the SV40 large T antigen, followed by growth first at the permissive temperature and then at the restrictive temperature, to halt proliferation. At column 12, first full paragraph, it is taught that the cells were then treated with vitamin D3.

As Applicant has not made and perfected a claim to priority to an earlier application, in that no priority claim is made in the first paragraph of the specification, the effective filing date of the instant application is 18 April 2001, which is its instant filing date. Were such a priority claim ultimately to be made and perfected, the rejection under 35 U.S.C. 102(e) would still remain in place.

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Claims 1-10, 13-17, 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Stringer (N, newly cited).

Stringer teaches, e.g., from page 32 through the first full paragraph at page 35, the temperature-sensitive immortalization of human embryonic cortex neural cells with a construct expressing a temperature-sensitive allele of the SV40 large T antigen, followed by growth first at the permissive temperature and then at the restrictive temperature, to halt proliferation. Subsequently, the cells were then treated with vitamin D3, dexamethasone or rabbit serum.

Claims 1-4, 6-10, 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Chou (U, newly cited).

Chou teaches, e.g., at page 1512, right-hand column, at the full paragraph, the immortalization of human epidermal cells with a temperature-sensitive mutant of SV40 T antigen, teaching that after growth at the permissive temperature, growth at the nonpermissive (restrictive) temperature leads to differentiation into keratinocytes.

Claims 1-4, 6-10, 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Lei et al. (V, newly cited).

Lei et al. Teaches, e.g., as summarized in the Abstract, the immortalization of human placental cells with a temperature-sensitive SV40 T antigen vector, followed by shift to the nonpermissive temperature, whereupon markers indicative of differentiation are observed.

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Claims 1-10, 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Whittemore et al. (AR, of record).

Claims 1-10, 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Whittemore et al. (AR, of record).

Whittemore et al. teaches, e.g., in the Abstract, the transfection of human oligodendrocytes and precursors thereof with a construct expressing a temperature-sensitive allele of the SV40 large T antigen, followed by growth first at the permissive temperature and then at the restrictive temperature, to halt proliferation.

As Applicant has not made and perfected a claim to priority to an earlier application, in that no priority claim is made in the first paragraph of the specification, the effective filing date of the instant application is 18 April 2001, which is its instant filing date. Were such a priority claim ultimately to be made and perfected, the rejection under 35 U.S.C. 102(a) would still remain in place.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-8 and 11-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The instant claims are drawn to methods that include a step of immortalization of cells followed by termination of the immortalization. The specification describes the use of conditional oncogenes for this pair of process steps. However, no description is present for any other mechanism by which a cell might be immortalized followed by the deliberate reversal of the immortalization. Claims 11 and 12 particularly recite a chemical or physical means of immortalization. However, no description is presented with respect to such means, particularly where reversible. Oncogenes would not constitute a representative sample of such means, as the mechanism of immortalization would be very different from chemical or physical means. Furthermore, oncogenes are reversible by virtue of the ability to cease expression. A mutation produced by a mutagen or by radiation would not be reversible by this mechanism, or indeed by any mechanism short of back-mutation. Immortalization by a compound not by mutagenesis, but by a shift in gene expression, e.g., a transforming growth factor, similarly would not be reversed by the mere removal of the compound. It is not apparent that reversible immortalization means were known in the art other than oncogenes, and therefore the mere description of a function would not have led one of skill to the structure of a means possessing that function. As such, the claimed invention would not have been described in such a way as to convey to one of skill in the art that Applicant was in possession of the full scope of the invention as claimed.

Claims 1, 4-8 and 13-27 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immortalizing agents which are oncogenes, does not reasonably provide enablement for other immortalizing agents. The specification does not

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As the grounds of rejection are effectively the same, the enablement rejections above are treated together.

The following factors have been considered in the rejection:

The amount of direction or guidance presented in the specification, the presence or absence of working examples. The specification does not describe immortalization means other than oncogenes, which are reversible as disclosed.

The nature of the invention, and the state of the prior art. The means by which the cell is immortalized must be deliberately reversible. Immortalization by mutation is by chance, and is reversible only by another chance event, i.e., a fortuitous back mutation. Immortalization by transforming factors generally does not reverse once the compound is withdrawn, as the cells have shifted states into an immortalized or transformed state.

The predictability or unpredictability of the art. As transformation or immortalization by mutation is a chance event, it is inherently a trial-and-error process, and thus unpredictable for any given cell or sample of cells. Therefore, reversal of the process by trial-and-error is equally, or even more so, unpredictable. If the entire sample of cells cannot have the immortalization reversed reliably, then the method will not be useable.

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Conclusion. Were the skilled practitioner to have endeavored to practice the claimed invention for other than oncogenes as the immortalizing agent, said practitioner first would have turned to the specification for guidance. However, as set forth above, the specification fails to set forth workable alternatives to conditional oncogenes. Next, said practitioner would have turned to the prior art for guidance in selecting an immortalizing agent. However, as set forth above, the other methods of immortalizing cells are not known to be easily or reliably reversible. Finally, the practitioner would have been forced to employ empirical experimentation to find other methods of reversibly immortalizing cells. However, neither the specification nor the art sets forth any alternatives to oncogenes for this purpose, and thus do not teach assays or routine methods for obtaining other such reversible immortalization means. Experimentation to find a means or structure which performs a desired function, where no examples or theory is available either from the specification or the prior art, would have been deemed undue experimentation.

Certain papers related to this application may be submitted to the directly to the Examiner by facsimile transmission at (703) 746-5155. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). To send the facsimile to the Art Unit instead, the Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant does submit a paper by fax to this number, the Examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the

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Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter two fax numbers unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk
April 18, 2003



**JAMES KETTER
PRIMARY EXAMINER**